

## REMARKS/ARGUMENTS

Claims 1-12 remain in this application. Claims 1, 5 and 9 have been amended. New claims 10 – 12 have been added. New claims 10 – 12 depend from claim 9.

### **Li, U.S. Patent No. 6,350,274**

The Examiner rejected claims 1-9 under 35 U.S.C. §102(b) as purportedly being anticipated by Li, U.S. Patent No. 6,350,274. The Examiner contends that Li discloses a portion of the closure element is distal of the distal opening. According to the Examiner, “[T]he distal end of the closure element is flush with the end of the tube; therefore at least a distal portion of the closure element is distal to hole 40. Additionally, as shown in fig. 4, at some point the closure element would be entirely distal to the hole 40.” (Office Action Page 3 and Li, Fig. 1.)

The applicant submits that the device disclosed by Li is substantially different than the device disclosed in the present application. With reference to Figures 1A – 3 of Li, the implant delivery device 12 includes two parallel tubes, a cannula 11 which contains the implant member 13 and a narrow tube 15 that includes a side hole 40 at the sealed distal end 39. When the end of the delivery device 12 is inserted into the blood vessel 44, blood flows into the side hole 40 and through the narrow tube 15. (Li, Col. 4, line 17 – Col. 5, line 11, Figs. 1A – 2A.)

Claim 1 has been amended to add the limitation that the occlusion member is in contact with the lumen of the elongate member. With reference to Figure 8, the application discloses that the occlusion member 220 is in contact with the lumen 232 at the distal end of the elongate member 235 and located distally of the distal opening 231. (Application, paragraph 0036, Figure 8.) Claim 1 was also amended to replace “it” with “said occlusion member” in order to

clarify that the blood flow is blocked when the occlusion member is withdrawn from the blood vessel lumen.

The applicant submits that Li does not disclose all limitations of claim 1. As discussed above, Li discloses an implant delivery device 12 that has two parallel tubes, a cannula 11 which contains the implant member 13 and a narrow tube 15, which has the side hole 40. The applicant submits that since the implant member 13 is positioned within the cannula 11, it is not in contact with the lumen of the narrow tube 15. For these reasons, the applicant submits that claim 1 is not invalid under 35 U.S.C. §102(b) as anticipated by Li. Claims 2-4 depend from claim 1 and are also not invalid as anticipated by Li.

Claim 5 is a method claim for installing a closure device. Claim 5 has been amended to more accurately describe the inventive installation method for the closure device. The preamble has been amended from “The method of installing a closure device adjacent to, but outside of a puncture in a blood vessel wall” to “The method of installing a closure device for sealing a puncture in a blood vessel wall.” The applicant submits that the amended preamble more clearly describes the context of the claim elements.

The applicant has also amended the introducing step limitation to add the requirement that the occlusion member is in contact with the lumen of the elongate member. This limitation is similar to the amendment of claim 1 and is supported by the specification, which discloses that the occlusion member 220 is in contact with the lumen 232 of the elongate member 235. (Application, paragraph 0036, Figure 8.) As also discussed above, the applicant submits that this limitation is not disclosed by Li because the implant member 13 is mounted in the cannula 11 and is not in contact with the lumen of the narrow tube 15. For the same reasons discussed

above in claim 1, the applicant submits that Li does not disclose all limitations of claim 5 and therefore claim 5 is not invalid under 35 U.S.C. §102(b) as anticipated by Li. Claims 6 and 7, which depend from claim 5. For these same reasons, claims 6 and 7 are also not invalid as anticipated by Li.

Claim 9 was amended to add the limitation that the lumen of the elongated member is aligned proximally over the occlusion member. Claim 9 was also amended to change the term “elongated member” to “elongate member” to correct a typographical error. As discussed above, the application discloses that the occlusion member 220 is in contact with the lumen 232 at the distal end of the elongate member 235 and located distally of the distal opening 231. (Application, paragraph 0036, Figure 8.) Because the occlusion member 220 is mounted at the distal end of the elongate member 235, the lumen of the elongate member 235 is aligned proximally over the occlusion member 220.

In contrast, Li discloses a cannula 11 that is parallel and offset from the narrow tube 15. Since the implant member 13 is placed within the cannula 11, the lumen of the narrow tube 15 is offset from the implant member 13. (Li, Figs. 1-6.) Thus, the applicant submits that Li does not disclose or suggest the limitation that the center axis of the elongated member intersects the occlusion member. For these reasons, claim 9 is not invalid under 35 U.S.C. §102(b) as anticipated by Li. New claims 10 – 12 depend from claim 9. For these same reasons, claims 10 – 12 are not invalid as anticipated by Li.

**Zhu, U.S. Patent Publication No. 2002/0072767**

The Examiner further rejected claims 1-4 and 9 under 35 U.S.C. §102(b) as purportedly being anticipated by Zhu, U.S. Patent Publication No. 2002/0072767. In the Office Action, the Examiner contends that Figure 6 of Zhu discloses a push member 84 having a plurality of distal openings 92 through the sidewall and in communication with the proximal opening 60.

Examiner argued that the occlusion member 80 and the push member 84 could be inserted into the blood vessel. Indeed, the Examiner contended that “[t]he fact that the hole 92 may be used to deliver an adhesive is irrelevant. If one placed the structure shown in Fig. 6 into a blood vessel such that hole 92 were inside the vessel, blood would enter hole 92 and travel up and out hole 90, or to the port which would accommodate a syringe or supply of adhesive. If the closure element were placed inside a vessel and then withdrawn, the closure element could easily plug a puncture opening. The examiner is not stating that doing so would be obvious.”

To more clearly describe the Zhu device, Figure 6 has been reproduced below:

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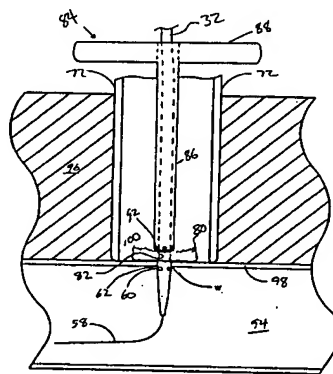


FIG. 6

The applicant respectfully disagrees with the Examiner's interpretation of the pending claims and the disclosure of Zhu. The functional limitations of the claims must be interpreted in view of a person of ordinary skill in the medical device art. As specified in MPEP section 2173.05(g), entitled "Functional Limitations:"

A functional limitation is an attempt to define something by what it does, rather than by what it is ... A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. Emphasis added.

The applicant submits that one of ordinary skill in the art would not interpret the functional limitations of claim 1 as being anticipated by Zhu in the manner described by the Examiner.

As illustrated above in Figure 6 of Zhu, the outer wall 98 of the artery 94 has a wound "w." A catheter 32 is placed over a guide wire 58 that was used for the insertion of an angioplasty. The tip of the catheter 32 is used to plug the wound and prevent blood from flowing from the blood vessel 94. Retractor arms 72 are used to draw tissue 96 away from the artery wall 98. The sponge 80 has a diameter much larger than the wound and a center hole that is placed around the catheter 32. The sponge 80 is pressed against the blood vessel 94 with a push member 84. Because the catheter 32 is plugging the wound hole, the sponge 80 surrounds the circumference of the wound. After the sponge 80 has been placed in contact with the vessel wall 98, the retractor arms 72 so that tissue covers the sponge 80. The catheter 32, guidewire 58 and push member 84 are then removed from the patient. The sponge 80 expands as blood is absorbed causing the sponge 80 to form clots to seal the wound. (Zhu, paragraphs 0047-0069.)

Claim 1 includes the limitation that the elongate member is “adapted to extend into a blood vessel such that said distal opening is located in the lumen of the blood vessel and such that blood flow through said proximal opening is visible outside of the patient's body.” The Examiner states that the sponge 80 could be placed in a blood vessel such that hole 92 of the push member 84 were inside the vessel. With reference to MPEP section 2173.05(g), the applicant submits that Zhu does not disclose inserting the push member 84 and sponge 80 into the blood vessel 94.

Zhu discloses that distal openings 92 in push member 84 provide a flow path for an adhesive that is used to secure the sponge 80 to the outer surface of the wound. Zhu also discloses that the push member 84 may be held in place until the adhesive cures and once the sponge 80 is correctly positioned over the blood vessel wall 98, the push member 84 can be removed. (Zhu, Paragraphs 0064, 0068, 0069) There are no other disclosed uses for the push member 84 and distal openings 92 in Zhu. Thus, Zhu does not disclose inserting the push member 84 and sponge 80 through the wound into the blood vessel 94. Because all claim limitations are not disclosed, the applicant submits that claim 1 is not invalid under 35 U.S.C. §102(b) as anticipated by Zhu. Claims 2-4 depend from claim 1 and are also not invalid as anticipated by Zhu.

Claim 9 is similar to claim 1 and includes the limitation, “said elongate member being adapted to extend into a blood vessel of a patient such that said occlusion member is fully inserted into the lumen of said blood vessel and said second opening is located in the lumen of the blood vessel such that blood flow through said proximal opening is visible outside of the patient's body.” For the same reasons discussed above in claim 1, the applicant submits that

there is no suggestion in Zhu for placing the push member 84 and the sponge 80 into the blood vessel 94. The applicant submits that claim 9 is not invalid under 35 U.S.C. §102(b) as being anticipated by Zhu. Claims 10 – 12 depend from claim 9 and for these same reasons, these claims are not invalid as anticipated by Zhu.

Although Zhu does not disclose all limitations of claims 1-4 and 9, the Examiner may argue that claims 1-4 and 9 would be invalid as obviousness under 35 U.S.C. §103(a). In order to find that any of the claims are invalid as obvious, the modification of the prior art reference must be suggested.

The applicant submits that Zhu does not provide any teaching, motivation or suggestion to a person of ordinary skill in the medical device art for modifying the use of the push member 84 or the sponge 80 for insertion through the wound and into the blood vessel lumen. The intent of the Zhu invention is to help heal the patient's wound and the device requires careful handling during use to avoid injuring the patient. Throughout the Zhu reference, the sponge 80 is only described as being placed against or bonded to an outer surface of the blood vessel wall 98 adjacent to the wound. (Zhu paragraphs 0058, 0059, 0063, and 0065.) More importantly, Zhu specifically discloses that the wound closure media sponge 80 should not be placed in the blood vessel because this will cause injury to the patient. According to Zhu, "if closure media extends through the wound and into the blood flow, this media can increase the likelihood of thrombus formation or could introduce potentially toxic substances into the bloodstream." (Zhu, paragraph 0040.) Thus, Zhu expressly teaches against inserting the sponge 80 into the blood vessel 94.

In addition to toxic effects, the insertion of the sponge would cause structural damage to the blood vessel. If excessive force is used or if the device is improperly used, the patient can be

easily injured. With reference to Figure 6, Zhu discloses that the tapered tip 40 of the catheter 32 is inserted into the blood vessel 94 to plug the wound. Thus, the cross section of the tip 40 of the catheter 32 is the same size as the wound w. The sponge 80 and the push member 84 surround the catheter 32 and are much wider in diameter. Since the catheter 32 fills the wound hole, the sponge 80 and the push member 84 are positioned over the blood vessel wall 98 around the wound hole and not over the wound hole. Thus, applying additional force to the push member 84 would only cause the sponge 80 to be inserted into the wound hole if the wound was expanded. This would result in injury to the patient.

For all of these reasons, the applicant submits that there is no suggestion in the Zhu reference of forcing the push member 84 and the sponge 80 into the blood vessel 94. Since Zhu does not meet all limitations of claim 1 including “said elongate member being adapted to extend into a blood vessel of a patient such that said distal opening is located in the lumen of the blood vessel,” the applicant submits that claim 1 would not be invalid under 35 U.S.C. §103(a) as obvious in view of Zhu. Claims 2-4 depend from claim 1 and the applicant submits that these claims would not be invalid as obvious in view of Zhu for these same reasons.

Claim 9 includes the limitation, “said elongate member being adapted to extend into a blood vessel of a patient such that said occlusion member is fully inserted into the lumen of said blood vessel.” As discussed above with respect to claim 1, the applicant submits that an obviousness rejection under 35 U.S.C. §103(a) requires a motivation or suggestion for modifying the teachings of the prior art reference. For the same reasons, the applicant submits that Zhu teaches against inserting the sponge 80 and push member 84 into the blood vessel 94. Thus, Zhu does not provide any teaching, suggestion or motivation for modifying the use of the push



member 84 for insertion into the blood vessel 94. Thus, the applicant submits that the push member of the Zhu reference does not meet the elongated member limitation of claim 9. Since Zhu does not disclose all limitations of claim 9 an obvious rejection under 35 U.S.C. §103(a) in view of Zhu would be improper. Claims 10 – 12 depend from claim 9 and would also not be invalid as obvious in view of Zhu.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned collect at (415) 705-6377 if there are any outstanding issues or questions which can be resolved to allow this application to be passed to issue.

Respectfully submitted,

DERGOSITS & NOAH LLP

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By:



Todd A. Noah

Reg. No. 35,626

Attorneys for Applicant  
Four Embarcadero Center, Suite 1450  
San Francisco, California 94111  
(415) 705-6377